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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,526	06/01/2001	Peter M. Bonutti	BON-1360-7	3309

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EXAMINER	
RAMANA, ANURADHA	
ART UNIT	**PAPER NUMBER**
3733	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/872,526	BONUTTI, PETER M.	
	Examiner	Art Unit	
	Anu Ramana	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36 and 38-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36 and 38-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/1/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The finality of the office action mailed on October 2, 2003 is being withdrawn due to the new rejections made in this action.

Response to Arguments

Applicant's arguments filed November 19, 2003 have been fully considered. The examiner agrees with the applicant that the term percutaneous means, "performed through the skin." However, the claims do not specify whose skin it is, i.e. the donor or fetus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson. Robertson discloses on page 444, paragraph 4, that fetal tissue may be used as an "effective therapy" for "severe chronic diseases." Robertson also discloses that the fetal tissue can be retrieved by suction curettage (page 496). Although it is not stated in the claims or the specification whether the donor is the fetus or the mother, the donor is considered the carrier or the mother. Robertson further discloses using the fetal tissue to treat the mother herself (page 457). Tissue retrieval is done percutaneously through the skin of the fetus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of U.S. Patent No. 3,804,089 to Bridgman.

Bridgman teaches a tool (Figs. 1-2) used for performing an abortion under the influence of suction (Abstract). Col. 2, lines 18-24 disclose that irrigation may occur either "constantly or intermittently." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Robinson in order to abort the fetus.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of U.S. Patent No. 3,804,089 to Bridgman, and in further view of U.S. Patent No. 5,190,541 to Abele et al. Bridgman is silent regarding the fact that irrigation and suction may alternate. Nevertheless, Abele teaches a surgical device that uses irrigation and suction, wherein the suction and irrigation alternate. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to alternate the suction and irrigation (through the same passageway) so that fewer instruments are required to pass through a surgical site.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of Bridgman (3,804,089) and in further view of Wuchinich (4,750,488). Bridgman

is silent regarding the fact that irrigation and suction may occur simultaneously. Nevertheless, Wuchinich teaches a surgical device wherein the irrigation and suction occur simultaneously. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the suction and irrigation simultaneous to complete the procedure more quickly.

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of Robinson (3,670,732). Robertson meets the limitations of the claims as described but fails to disclose a method of removing the fetus. Nevertheless, Robinson discloses a method of removing the fetus, wherein the tissue is sucked while rotating and reciprocating motion are used to cut the tissue (Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Robinson in order to abort the fetus.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of Bridgman (3,939,835). Robertson meets the limitations of the claims as described but fails to disclose a method of removing the fetus. Nevertheless, Bridgman teaches a method of aspirating and removing an aborted fetus, including the passage (the collection bottle) having a filter 14 (col. 4 lines 65—col. 5 line 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Bridgman in order to abort the fetus.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of U.S. Patent No. 3,939,835 to Bridgman, and in further view of U.S. Patent No. 4,883,666 to Sabel et al. The Robertson/Bridgman method fails to disclose centrifuging the fetal tissue. Nevertheless, Sabel teaches that the "implantation of developing nerve tissue obtained from rat fetus and implanted into brain-damaged host animals reduces

behavioral deficiencies due to the lesions." Although rat fetal tissue was mentioned as the tissue source, in col. 2, lines 5-6, Sabel implies that human tissue could be used but would not be due to ethical concerns. Moreover, Robertson teaches that human fetal tissue may be used. In any event, centrifuging must have occurred in order to isolate nerve tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to centrifuge the fetal tissue in order to isolate the nerve tissue.

Claims 36, 45-46, 49-50 and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,863,472 to Tormala et al. in view of Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson. Tormala et al. discloses the steps of combining bone tissue (e.g. allografts) with a bone growth promoting substance (e.g. hydroxyapatite) and forming an implant (e.g. col. 7, lines 16-55). However Tormala et al. fails to disclose the bone tissue as fetal tissue. As noted above, Robertson teaches the use of tissue from fetal organs retrieved under suction for implantation. Robertson further teaches that fetal organs include bone (page 473). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the use of fetal bone tissue to the implant of Tormala et al. because histocompatibility between the tissue source and its recipient is not necessary for effective transplants (Robertson- page 456). In addition, the use of x-ray guidance, such as with fluoroscopy, or arthroscopes for orthopedic surgery, was well known to those of ordinary skill at the time of invention. In addition the use of cannulae during to gain better access to the uterus during retrieval was well known to those of ordinary skill at the time of invention.

Claims 47, 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,863,472 to Tormala et al. in view of Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson, as above, in further view of Bosch et al. (The technic of fibrin glue in ...) Tormala/Robertson disclose the claimed subject matter as noted supra, however they fail to disclose the use of fibrin adhesive.

Bosch et al. teach the use of fibrin adhesive with bone grafts. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the use of fibrin sealant to the methods disclosed by of Tormala/Robertson because the fibrin sealant provides "exact local hemostasis, adhesive strength, and plasticity" (Bosch et al.).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached on Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
October 5, 2007

ANURADHA RAMANA
PRIMARY EXAMINER
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